DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)

June 23, 2000

Dear Offeror(s):

Subject: Request for Proposals (RFP) 2000-N-00073

In response to the instructions Section L.6, Inquiries, of the subject RFP, several prospective offerors submitted a number of questions concerning the solicitation document. Below for your information is a list of those nine questions and the Government's responses to them.

Sincerely,

Kem Williams
Contract Specialist
Procurement and Grants Office

Enclosure

SOLICITATION 2000-N-00073
Questions from Potential Offerors and Answers from the Government

1. **Question**:
Section CIV Phase C implies that reporting is required but does not give an indication as to the test program to be utilized. Is testing part of this phase or is it part of the subsequent phases D to F?

Answer:
The final working prototypes submitted in satisfaction of Section C.IV, Phase C (Working Prototypes, page 4) and section F.1, Phase C (Working Prototypes), item 6, page 9 should already have been preceded by bench testing data of physical parameters and *in vitro* performance submitted from Section C.IV, Phase B (Initial Prototype, page 4) and section F.1, Phase B (Initial Prototype), item 5, page 9. However, the Government recognizes that design and development are iterative processes and that the working prototypes submitted at the conclusion of phase C may have further refinements and design changes made subsequent to phase B. In such case, or if phase C is itself the first phase contracted with the Government by a company with prior technology, then the phase C report should include updated bench testing results on the working prototypes (or complete results if not previously reported).

The specific physical parameters and in vitro performance data ("performance profile") to be provided in phase B are not specified by the Government, but left to the determination of the offeror. However, the tests planned should be described in the technical proposal by the offeror. As further clarification, such bench testing may – but not necessarily – include parameters such as pressure, force, volume, velocity, time, distance, movement, depth or dispersion of penetration, and stream cross-section or silhouette, among others, which may be measured with suitable internal and external recording devices (e.g. transducers, strobe photography, etc.) or *in vitro* models.

The reports for the results of the testing of these working prototypes in subsequent phases D, E, F, G are not a deliverable for this phase C. The deliverables for phase C consist only of the prototype devices and accessories themselves and corresponding bench testing results if not already reported in phase B, as explained above.

2. **Question**:
Section C.IV A required CAD Drawings 3 months After Award of Contract. Section F.1 requires CAD drawings 6 months After Award of Contract. Please clarify.

Answer:
To correct this inconsistency in the announcement, Section C.IV, phase A (page 4) and section F.1, Phase A (Initial Design), item 2 (page 9) should both be read as specifying "initial, preliminary, conceptual" CAD drawings at 3 months after award of contract, as part of phase A. Section C.IV, phase B (Initial Prototype, page 4), and section F.1, Phase B (Initial Prototype), item 3 (page 9) should be read as specifying "detailed" CAD drawings, as part of phase B.

3. **Question**:
On page 4, Section IV, Phase A, initial design calls for CAD drawings following acquiring background information. Phase B calls for building the functional prototype.

However, one page 9, F.1 Deliverables, Item 2, Phase A: Initial Design only calls for reports, not CAD drawings. The drawings here appear under Phase B.

Are the prototype drawings part of Phase A or Phase B?

Answer:
Same answer as for question 2. above.

4. **Question**:
Please confirm whether the doses are administered intramuscularly or subcutaneously in the USA. (Note: In Europe, the doses are administered subcutaneously…).

Answer:
Licensed measles vaccines in the United States are administered subcutaneously, as are most all other attenuated live virus vaccines admininistered parenterally (mumps, rubella, measles-mumps-rubella, varicella, yellow fever). However, to broaden the marketability of a needle-free injection device, manufacturers might want to consider flexible designs that would permit future modifications capable of deeper (intramuscular) injections for other vaccines. This, however, is not a requirement of this RFP.

5. **Question**:
Please confirm the delivered volume of vaccine.

Answer:
The typical volume of reconstituted liquid measles vaccine administered worldwide is 0.5 mL. However, to broaden the marketability of needle-free injection devices, manufacturers might want to consider flexible designs that would permit future modifications capable of delivering volumes up to 1.0 mL, which is used for a few vaccines other than measles. This, however, is not a requirement of this RFP.

6. **Question**:
This is a negotiated cost contract. Is there a maximum amount of funding allocated to this project, by phase or in total, that we should be award of.

Answer:
This acquistion is anticipated to be awarded as a negotiated cost contract. There is a maximum funding profile that is not releasable to the public. Offerors are expected to submit an independent competitive technical and cost proposal.

7. **Question**:
Phase G, field testing, it is very difficult to come up with cost estimates for such an extensive program, particularly since it is to be done in consultation with CDC. How should these costs be handled?

Answer:
The Government recognizes there are many variables in study design and country selection inherent in Section C.IV, Phase G (Field Testing, page 5), and Section F.1, Phase G (Field Testing, page 10) which would require consultation with CDC and other parties, and thus subject to modification and negotiation in design and cost. However, for purposes of offers under this contract solicitation, an offerer should propose its own study design for such field testing in terms of research questions to be answered, the nature and size of subject groups to be sampled and/or queried, examples of countries with endemic measles appropriate for mass vaccination campaigns proposed for the field testing, and a proposed budget for same, as a starting point for negotiation and an indication of experience and understanding by the offeror of the nature of such work.

8. **Question**:
The instructions indicate that due to the severability of contract phases, we should submit separate technical and business proposal sections for each phase, which could be handled as stand-alone contracts. Under section L.10(c)2, it also states that the technical proposal should be prepared in a format which mirrors the evaluation criteria, i.e., Understanding of the project, Methodology and Approach, etc.

Does this mean that we need to submit separate technical proposals for each Phase A-H and within each separate proposal also address each specific evaluation criteria? For example:
Phase A-Initial Design

Should we submit a business and technical proposal for this phase and address all of the evaluation criteria within it?

Answer:
Separate business and technical proposals should NOT be submitted for each phase. Rather, the offeror should submit one (1) overarching technical proposal for all phases, with individual sections therein, as needed, to address specific issues within each phase. However, the business proposal shall be costed out by phase, with additional cost details, if possible, for major components within each phase.

9. **Question**:
Section C-III, paragraph A.4. states a "…target age for measles and rubella immunication (9 months through 15 years of age);"

However, Section C-III, paragraph A.8. and Section C-IV, Phase F discusses children between 9 months to 15 months of age.

Which age group is correct?

Answer:
For purposes of ultimate use of the device developed under this contract for global "catch-up" programs to eradicate measles, which includes older children who missed vaccination at the recommended ages, the device should be suitable for use in the full age range of 9 months to 15 years. However, for purposes of the clinical human studies of the device in children requested in section C.14, Phase F (page 5), and section F.1, Phase F, item 9 (page 10), the age range is limited to the recommended ages for children to receive measles vaccine in routine immunization programs in developing countries: 9 to 15 months of age. This should simplify the conduct of such a study, which may, however, be conducted in either a developed (e.g., USA) or developing country, whichever is more convenient and feasible.

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